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CONFIRMATION COPY

Dear Sirs,

Re. : INDIA – PCT Application No. PCT/IN04/00142

Dated – May 20, 2004

Claiming Priority on IN/PCT/04/000064 dated 19/3/2004 and
563/MUM/2004 dated 17/5/2004

For – "AN IMPROVED PROCESS FOR PRODUCING CHLORI-NATED SUCROSE"

By – Dr. Rakesh Ratnam; Shrikant Kulkarni & Suneet Aurora.

With reference to your International Search Report dated March 2, 2005,
we are amending the claims.

Please take a note of following matters :

1. Replacement sheets containing amended claims and bearing page numbers 29 to 31.
2. Page No. 29 of the original application has been completely replaced by new sheet of same page number, and two more sheets have been added at page Nos. 30 & 31.
3. Amendment to claims: Claims 1 to 23 unchanged; amended claims 24 to 31 replace claims 24 and 25 as filed.
4. A "Statement under Article 19(1) Rule 46.4" has also been annexed herewith, which the applicant desires to be taken into consideration for publication as well as for International Preliminary Examination Report when demand for the same shall be made before the deadline for the same.

FOR KRISHNA & SAURASTRI

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Encl. : As above.

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Statement under Article 19(1) (Rule 46.4)

With respect to International Application no. PCT/IN2004/000142

The inference of the Authorised officer that there is no novelty and inventive step in the subject matter of claims 24 and 25 is based principally on the reason given in his report as "The document D1 and D2 disclose the synthesis and isolation of sucralose, thus claims 24 and 25 lack novelty since the product by process must be new and inventive. A product is not rendered novel merely by the fact that it is produced by a new process."

We request to invite attention to the fact that the said "A product or composition" of claim no. 24 and "A product or composition of claim no. 24" as referred in the original claim nos. 24 and 25 refer not to "sucralose" as chemical entity but to the novel amorphous form of chlorinated sucrose (sucralose), its intermediates and its derivatives, which has different appearance and physical properties than the conventional crystalline forms and is not reported in the prior art. They relate to the disclosures made at two places in the above referred PCT application: (1) at line 13 to 18 of first paragraph on page no. 3 ("The final powder of the product are being studied") and (2) at the last paragraph on page no. 16 ("The solids isolated were, however, amorphous in nature having smaller particle size.").

The said novel form is amorphous in appearance to naked eye, seen to have flow properties and storage stability properties which are exclusively different than the prior art and open up a wide range of commercial applications which

originate as spin off from the new physical properties. The new forms are also diagnostic of the process used for their production, which itself is of commercial value in protecting the new process described in claims 1 to 23. Hence, the new forms need to be and qualify to be protected by patent claims as they have novelty, inventive step as well as industrial applicability.

In electron microscopic examination the said amorphous form comprises particles which are in the nature of either pure amorphous, microcrystalline with several shapes or transitional types. When they are of microcrystalline or transitional types, most of the particles are of particle size lesser than 20 microns, more than 90% particles being of size lesser than 12 microns.

To make the reference more explicit, both the claims nos. 24 and 25 are now replaced by amended claim nos. 24 to 31 which incorporate the subject matter of the original claim nos. 24 and 25 by redrafting, which involves bringing the relevant details in the draft of claims proper and by suitable subdivision of the details.

There will be no effect of these amendments in claims on drawings. However, it would be necessary to add information giving details of observations on particle size distribution and storage properties in the description.

For International Preliminary Examination, applicant wishes these amendments be taken into account.

22. The process of claim 11 wherein the said impure solution is the solution of the solid powder mixture of several chemicals, including chlorinated sucrose, made in water and subjected to purification by application of separation methods including column chromatography.
- 5 extraction in water immiscible solvent having selective affinity with chlorinated sucrose or chlorinated sucrose intermediates or chlorinated sucrose derivatives
23. The process of claim 11 when the said impure solution is the crude extract of chlorinated sucrose (or its intermediates or derivatives) from a solid powder mixture of several chemicals, including chlorinated sucrose; extraction being done by water and the water extract being subjected to any suitable extraction process including to conventional extraction in any suitable solvent, including ethyl acetate, methanol, methyl ethyl ketone, acetone, which are capable of selective extraction of substantially pure form of chlorinated sucrose free from impurities.
- 15
24. Chlorinated sucrose, its intermediates, its derivatives of process of claim 1 to claim 23, at least part of which is amorphous or non crystalline.
25. Chlorinated sucrose, its intermediates, its derivatives of claim 24 produced by process of claim 1 to 23.
- 20 26. Chlorinated sucrose, its intermediates, its derivatives of claim 24 which comprises of :

- i) average particle size of 8 micron or less, within a range of 5 micron to 8 micron.
- ii) residual moisture content of 10% or less, more particularly less than 5%, still more particularly less than 0.5%.

5 27. Chlorinated sucrose, its intermediates, its derivatives of chlorinated sucrose, its intermediates, its derivatives, at least a portion of which comprises of particles less than 20 micron precipitated as microcrystalline particles directly from a process of crystallization.

10 28. Chlorinated sucrose, its intermediates, its derivatives of claim 27 produced by process of claim 1 to 23.

29. Chlorinated sucrose, its intermediates, its derivatives of claim 27 which comprises of:

- i) average particle size distribution of 12 micron or less within a range of 8 micron to 10 micron
- 15 ii) various shapes ranging from globular particles to fully crystallized needles
- iii) residual moisture content of 10 % or less, more particularly less than 0.5%, still more particularly less than 0.3%

30. Chlorinated sucrose, its intermediates, its derivatives at least a part of which consists of amorphous or non crystalline or of particles less than 20

micron microcrystalline particles produced directly from a process of crystallization.

31. An oral composition, ingestible as well as non-ingestible including a toothpaste and a chewing gum, a food, a beverage; high intensity sweetener composition; in solid, semi-solid or liquid form, to which is added a composition of chlorinated sucrose one or more of claim 24, claim 25, claim 26, claim 27, claim 28, claim 29, and claim 30.